

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION OF JOSEF REITTER UNDER 37 C.F.R. § 1.132

APPLICANTS: Reitter et al. CONFIRMATION NO. 7116
SERIAL NO.: 09/809,958 GROUP ART UNIT: 3737
FILED: March 16, 2001 EXAMINER: Ruth S. Smith
TITLE: "APPARATUS FOR GENERATING ACOUSTIC WAVES"

Commissioner for Patents
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S I R:

I, JOSEF REITTER, declare as follows:

1. I am one of the inventors named in the above-referenced patent application.
2. I am a graduate engineer (University of Applied Sciences) and have been employed since 1980 by Siemens AG as a development engineer in the field of x-ray technology.
3. In studies in which I participated with respect to the subject matter of this application, a test set-up as shown on Attachment "A" hereto was used to determine the influence of the acoustic transducer on an x-ray image, obtained through the acoustic transducer, of a typical kidney stone patient.
4. In the setup shown in Attachment "A", an iron film or membrane having a thickness of 0.2 mm, and a Plexiglas® film or membrane having a thickness of 5 mm correspond to the acoustic transducer. The 20 cm thick Plexiglas® body corresponds to the patient. No significant impairment of the x-ray image produced with this set up was noted.

5. Subsequently, numerical results were obtained using the commercially available software Boone-1.1 ("Generation of A Normalized Photon Energy Spectra for a Variety of Anode Material and Filters and Calculation of Contrast and CNR Values"), which is based on Internationally recognized algorithms and material data (National Institute of Standards and Technologies - NIST).

6. Using this software, I determined that, for an X-ray radiator with a tungsten anode, operated at 70 kV with 2.5 mm aluminum pre-filtering, and using a 20 cm water equivalent (corresponding to an average patient, an additional aluminum foil (additional pre-filtering) having a thickness of 150 μm has the same attenuation as an additional layer of 0.75 mm water (water equivalent), and I further determined that an additional iron foil or membrane (representative of stainless steel) having a thickness of 150 μm has the same attenuation as an additional layer of 12 mm water (water equivalent).

7. Since 0.75 mm water and 12 mm water have virtually no attenuation effect on x-rays passing therethrough, I determined that a membrane or foil of aluminum or stainless steel having the aforementioned thickness can be used in an acoustic wave generator without significant impairment of an x-ray image of a patient to be treated, obtained by passing x-rays through such a membrane or foil.

8. Since the degree of attenuation is also dependent on the mAs value at which the x-ray source is operated, I realized that strict adherence to the aforementioned 150 μm thickness of the aluminum or stainless steel membrane was not necessary, and that successful results are obtainable as long as the aluminum or stainless steel membrane has a thickness in the micrometer range. Moreover, since the aluminum or stainless steel foil or membrane in the lithotripter would be disposed between the patient and the x-ray source, even if a higher mAs value were employed, this would not result in any significant increase in the x-ray dose to the patient.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this verified statement is directed.

DATE: X 02.12.04

X [Signature]
JOSEF REITTER

Test setup

